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| 10/526,238 | 10/21/2005 | Jan Henrik Ardenkjaer-Larsen | PS0267 | 8175 |
| 36335 7590 08/14/2008 GE HEALTHCARE, INC. IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231 | | | | |
| EXAMINER | | | | |
| SCHLIENTZ, LEAH H | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,238

Applicant(s)

ARDENKJAEER-LARSEN ET AL.

Examiner

Leah Schlientz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-12 is/are pending in the application.
4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 3-6 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 28 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 1/23/08 is acknowledged.

Status of Claims

Claims 1 and 3 – 12 are pending, of which claims 7 – 12 are withdrawn from consideration at this time as being drawn to a non-elected invention. Claims 1 and 3 – 6 are readable upon the elected invention and are examined herein on the merits for patentability.

Claim Objections

Claim 1 is objected to because of the following informalities: the claim includes a typographical error such that two periods occur at the end of the sentence. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3 – 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method for producing an MR contrast agent, the method comprising the steps of: -obtaining a solution in a solvent of a hydrogenatable, unsaturated substrate compound and a catalyst for the hydrogenation of a substrate compound, wherein the substrate compound comprises imaging nuclei. However, the specification does not provide description of the claimed hydrogenatable, unsaturated substrate compound required to make and use the contrast agent as broadly claimed. There is no description provided regarding which types of specific chemical moieties are used to represent the substrate that would render such a compound to be useful as a contrast agent. There is very little predictability in the art concerning any undefined species which may represent a substrate compound and furthermore, one of ordinary skill in the art would not know which chemical moiety would represent a substrate out of an almost unlimited number of chemical species which may be possible. The specification does not provide any guidance to the specific identity or physical / chemical structure of the variables which represent a substrate, and because the structures and physical identities of these elements are undefined, it is unclear how Applicant envisaged suitable elements to satisfy the functional requirements of the substrate. It is noted that the specification refers to suitable substrate materials as those found in WO 99/24080, however, the

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incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3 – 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a method for producing MR contrast agent comprising the steps of *-obtaining* a solution in a solvent of a hydrogenatable, unsaturated substrate compound...; *-hydrogenating* the substrate...; and *-exposing* the contrast agent to a sequence of pulses of magnetic field for enabling spin-order to be transferred from the protons in the hydrogenated contrast agent to polarization of a nucleus within the same molecule... wherein the exposing step comprises the steps of *-placing* (300) a dose or part of a dose of contrast agent in a magnetic field treatment chamber (245)...; *-subjecting* (305:1-305:N) the dose ...; – *applying* (310) the dose..., etc. steps. The numbers included in parenthesis appear to

refer to various figures in the specification (see Figures 1 – 3). However, where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table “is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant’s convenience.” *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted). Reference characters corresponding to elements recited in the detailed description and the drawings may be used in conjunction with the recitation of the same element or group of elements in the claims. See MPEP § 608.01(m). See also 2173.05(s). In the instant case, the claims appear to be adequately described using text and the reference to the figures via various step numbers is unnecessary. It is respectfully suggested that the claims should be amended to remove the step numbers and apparatus numbers in parentheses.

Claims 1 and 3 – 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10

USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "one or more subsequent pulses," and the claim also recites "two subsequent pulses" which is the narrower statement of the range/limitation. Furthermore, the claim is confusing because it is unclear what the minimum number of required pulses may be. For example, after the placing (300) step, the subjecting step (305:1-305:N) occurs, whereby the contrast agent is subjected to a first pulse of magnetic field, and to one or more further subsequent pulses of magnetic field, wherein two subsequent pulses differ in a parameter. It is unclear whether the "two subsequent pulses" refers to the first pulse after exposure to earth's field and one additional pulse (e.g. minimum of two total pulses required in the subjecting step); or if the "two subsequent pulses" means two subsequent pulses occur after the first pulse of magnetic field (e.g. minimum of three total pulses required in the subjecting step). For the purposes of prior art search, the examiner has interpreted the claim such that the two subsequent pulses refer to a first pulse and one subsequent pulse during the subjecting step which differ in at least one of strength, orientation or duration (e.g. a minimum total of two pulses during the subjecting step).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 – 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Axelsson *et al.* (WO 00/071166, whereby US 6,872,380 is relied upon as equivalent).

Axelsson discloses a process for the preparation of an MR contrast agent comprising: (i) obtaining a solution in a solvent of a hydrogenatable, unsaturated substrate compound and a catalyst; (ii) introducing said solution in droplet form to a chamber containing hydrogen gas enriched in para-hydrogen and/or orthodeuterium, whereby to hydrogenate said substrate to form a hydrogenated imaging agent; (iii) optionally subjecting said hydrogenated imaging agent to a magnetic field strength below earth's ambient field strength (column 2, lines 39+). Preferably, the low field treatment may be effected by passage through a magnetically shielded area with a special magnetic field profile. The sample leaves earth's magnetic field and enters an area with a field lower than 0.1 μ T in just a few ms. The sample is then gradually returned to the earth's magnetic field. This effects an efficient transfer of polarization from protons to the hetero-nucleus (column 3, lines 20 - 33). The sample should leave the earth-field suddenly (i.e. a rapid decrease in magnetic field), which means on the order of 1 ms. The sample should then gradually return to earth field (i.e. increase in

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field, or a subsequent pulse differing in magnetic strength, as claimed), meaning on the order of 10-10000 ms, preferably 100-1000 ms. With regard to the instant claims, dependent claim 3 defines a pulse as a rapid increase or rapid decrease in magnetic field. Accordingly, Axelsson meets the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 3 and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 11 of copending Application No. US 10/526,240. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are drawn to a method of producing an MR contrast agent comprising the steps of obtaining

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a solution of a hydrogenatable, unsaturated compound, hydrogenating with parahydrogen enriched hydrogen gas, and exposing the contrast agent to a magnetic field. With regard to the exposing step, the '240 application requires an initial decrease in magnetic field followed by at least one increase of magnetic field and that of the instant application requires placing the contrast agent in a magnetic field on the order of earth's magnetic field and subjecting the contrast agent to subsequent magnetic field having different strength, orientation or duration to that of the earth's field and returning to earth's field. Accordingly, the claims are overlapping in scope and are obvious variants of one another. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS